UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CENTRAL STATES, SOUTHEAST AND SOUTHWEST AREAS, HEALTH AND WELFARE FUND,

Plaintiff,

v.

SMITHKLINE BEECHAM CORPORATION and GLAXOSMITHKLINE PLC,

Defendants.

04-10817 WGY

MAGISTRATE JUDGE Cohen

RECEIPT #
AMOUNT $ 150
SUMMONS ISSUED 2
LOCAL RULE 4.1
WAIVER FORM
MCF ISSUED
BY DPTY. CLK.
DATE 4-26-04

COMPLAINT

Plaintiff, upon personal knowledge as to facts pertaining to itself, and upon information and belief as to all other matters, alleges as follows:

NATURE OF THE ACTION

1. This complaint alleges violations of federal antitrust law and state antitrust and unfair and deceptive trade practices acts arising from the manufacture and marketing of Relafen, a brand name drug. Relafen is a non-steroidal anti-inflammatory drug ("NSAID") which is used in the treatment of certain diseases characterized by inflammation, especially arthritis. The active ingredient in Relafen is nabumetone. Until August 2001, no brand name drug based on nabumetone and no generic version of Relafen was marketed in the United States. This is because Defendants unlawfully obtained and enforced a monopoly for Relafen and nabumetone through intentional misrepresentations to the U.S. Patent and Trade Mark Office ("PTO"). Defendants obtained a patent for nabumetone and caused it to be listed in the *Orange Book* (defined below) in a manner which has enabled Defendants to falsely

create and extend their market monopoly for Relafen and nabumetone. Defendants further engaged in sham litigation to unlawfully enforce their patent, although they knew that the patent was invalid. As a result of Defendants' conduct, Plaintiff paid thousands of dollars for Relafen at supra-competitive prices that it would have saved had competing and/or generic versions of Relafen been available.

2. Plaintiff seeks equitable, injunctive and declaratory relief against Defendants based on allegations of monopolization of, and an attempt to monopolize, the market for Relafen and generic bioequivalents of Relafen, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

3. Plaintiff also seeks relief pursuant to the antitrust and unfair and deceptive trade practices acts of the Indirect Purchaser states in which it operates.

4. Plaintiff further seeks a constructive trust and disgorgement of the unjust enrichment of Defendants.

JURISDICTION AND VENUE

5. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of the federal antitrust laws, including Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

6. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because Defendants transact business, are found, and/or have agents in this district; because a substantial portion of the affected trade and commerce described below has been carried out in this district; because Defendants brought the sham litigation which forms an integral part of these claims in

this district; and because other related actions are pending in this district.

7. The illegal monopolization and attempt to monopolize the market for Relafen and generic versions of Relafen, as alleged herein, have substantially affected interstate and foreign commerce.

PARTIES

8. Plaintiff Central States, Southeast and Southwest, Health and Welfare Fund ("Plaintiff" or "the Fund") is a trust fund established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. §186(c)(5), and is an employee benefit plan established and maintained pursuant to the Employee Retirement Income Security Act, 29 U.S.C. §1001 *et seq.*, for the purpose of providing health benefits, including prescription drug coverage, to eligible participants and beneficiaries. The Fund maintains its principal place of business at P.O. Box 5111, Des Planes, Illinois 60017.

9. Plaintiff has paid, at supra-competitive prices, for some or all of the cost of Relafen prescribed to one or more of its participants or beneficiaries, and has thereby been injured, and continues to be injured, as a result of Defendants' conduct.

10. Defendant SmithKline Beecham Corporation is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, doing business as GlaxoSmithKline. Its principal place of business is at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania 19102. It is engaged in the business of research, development, manufacture and sale of pharmaceutical products throughout the world.

11. Defendant GlaxoSmithKline PLC is a United Kingdom corporation with its principal

offices located at Glaxo Wellcome House, Berkeley Avenue, Grenford, Middlesex, UB6 ONN, United Kingdom. GlaxoSmithKline was formed following the December 2000 merger of SmithKline Beecham PLC and Glaxo Wellcome PLC. Together with SmithKline, GlaxoSmithKline manufactures and markets Relafen throughout the United States. Collectively, Defendants are referred to herein as "Defendants" or "SmithKline."

INTERSTATE TRADE AND COMMERCE

12. During all or part of the relevant time period:

(a) Defendants manufactured and sold substantial amounts of Relafen in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States;

(b) Defendants transmitted funds, as well as contracts, bills, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Relafen; and

(c) Defendants employed, in furtherance of their monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

RELEVANT MARKETS

13. As to the claims so requiring, the relevant product market is the market for the manufacture and sale of Relafen, nabumetone, and all generic bioequivalents rated "AB" by the United States Food and Drug Administration ("FDA"). The relevant geographic markets are the United States and its territories as a whole (Counts I and IV) and the Indirect Purchaser States (Counts II and III).

At all relevant times until August 20, 2001, Defendants' market share in the relevant product and geographic markets was 100%.

14. Relafen and generic nabumetone products are not reasonably interchangeable with other NSAIDs. Each NSAID may cause a variety of side effects, the most common of which are gastrointestinal side effects, including diarrhea, dyspepsia and abdominal pain. Relafen and generic nabumetone products produce gastrointestinal (and other) side effects in a significant subpopulation of patients to an extent and in a manner that differ substantially from, and are less severe than, the gastrointestinal (and other) side effects of other NSAIDs. Relafen's gastrointestinal effects are noted, at least in part, in the FDA-approved informational insert that accompanies Relafen.

FACTUAL ALLEGATIONS

A. Brand-Name Drugs vs. Generic Drugs

15. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The United States market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at a rate of 14% to 18% per year, and the cost of drugs dispensed in the United States for the year 2001 was in the range of $160 billion to $170 billion.

16. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

17. Generic drugs are normally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payors between $8 billion and $10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed, "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."

18. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

19. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

B. The Federal Scheme For Approval Of Pioneer Drugs

20. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act"), approval by the FDA is required before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "brand-name" drug, must be sought by filing a New Drug Application ("NDA") with the FDA, demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus

any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 ("Hatch-Waxman Act").

21. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all "prior art," as well as patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted. "Prior art" is the term used in patent law to refer to that body of previous knowledge and technology against which a patent application is judged to determine whether the claim is sufficiently novel to merit patent protection. When the NDA is approved, the FDA "shall publish" the patent information submitted by the NDA applicant. 21 U.S.C. § 355(b)(1).

22. Once the NDA is approved, the FDA lists any patents referenced as part of the NDA application process in a publication known as the *Approved Drug Products With Therapeutic Equivalence Evaluations*. This publication is commonly called the "*Orange Book*."

23. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-related generic version of that pioneer drug which has been approved by the FDA is available.

C. Generic Drugs

24. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a

generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

25. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

26. Once a physician writes a prescription for a brand-name drug such as Relafen, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

D. Abbreviated New Drug Applications For Generic Drugs

27. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug. The Hatch-Waxman Act also provides an economic incentive to the first generic drug manufacturer to file an ANDA for a particular generic drug of a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from

competition from other generic manufacturers.

28. The ANDA must include information concerning the applicant's position *vis-a-vis* the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications:

I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

II. that the patent for the pioneer drug has expired (a "Paragraph II Certification");

III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV Certifications.

29. If the ANDA contains a Paragraph IV Certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification, and to the holder of the approved NDA to which the ANDA refers. *See* 21 U.S.C. § 355(j)(2)(B)(i). The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's assertion that the patent is not valid or will not be infringed by the generic product. *See id.*; 21 C.F.R. § 314.95.

30. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. *See* 21

U.S.C. § 355(j)(5)(5)(iii). If no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

31. Accordingly, brand-name drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.

E. Defendants Made Intentional Misrepresentations to the PTO and Engaged in Sham Litigation to Obtain and Maintain an Improper Monopoly for Relafen and Nabumetone

32. Defendants are the owner of Patent No. 4,420,639 (the "'639 Patent") which purported to cover the chemical compound nabumetone. Pursuant to NDA No. 19-583, Defendants have marketed Relafen, whose active ingredient is nabumetone, in the United States and elsewhere since February 1992. The '639 Patent is the issued patent from the last of a chain of six U.S. patent applications. The original term of the '639 patent was extended for two years. As extended, the patent expired on December 13, 2002.

33. Copley Pharmaceutical, Inc. ("Copley"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Eon Labs Manufacturing, Inc. ("Eon") (collectively the "Generic Manufacturers") are each manufacturers of generic pharmaceutical products. Each filed an ANDA with the FDA to market generic versions of Relafen.

a. On August 4, 1997, Copley filed ANDA No. 75-179, the first ANDA for a

generic version of Relafen 750 mg with a Paragraph IV Certification that the '639 Patent was either invalid or not infringed.

b. On August 18, 1997, Teva filed ANDA No. 75-189, the first ANDA for a generic version of Relafen 500 mg with a Paragraph IV Certification that the '639 Patent was either invalid or not infringed. Teva acquired Copley on August 10, 1999, bringing together the ANDAs for both the 500 mg and 750 mg strengths of generic Relafen.

c. On December 18, 1997, Eon filed ANDA 75-280 for a generic version of Relafen 500 mg and 750 mg with a Paragraph IV Certification that the '639 Patent was either invalid or not infringed.

34. The Generic Manufacturers each gave written notice ("notice of certification") to SmithKline, pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii), that its ANDAs and the accompanying certification had been filed with the FDA. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notices also set forth the legal and factual bases for their claims that the '639 patent is invalid and/or unenforceable.

35. Within forty-five days of receipt of each of the notices of certification, Defendants brought suit for infringement of the '639 patent (hereinafter referred to collectively as the "Infringement Actions"). The filing of the first of the Infringement Actions resulted in an automatic 30-month stay of the FDA's authority to grant final marketing approval to each of the Generic Manufacturers that filed ANDAs. Thereafter, the FDA could not grant final marketing approval to Teva's and Copley's ANDAs until they prevailed in the Infringement Actions or until at least 30 months expired, whichever was sooner.

36. On October 27, 1997, SmithKline commenced a lawsuit against Copley in the District of Massachusetts, alleging that Copley's 750 mg nabumetone product infringed its '639 Patent.

37. In November 1997, SmithKline commenced an action in the District of Massachusetts for infringement against Teva. On December 18, 1998, Teva filed and served its answer in that action and commenced a counterclaim suit against SmithKline. Teva asserted in its counterclaim suit that the '639 Patent was invalid as anticipated by prior art and sought a declaratory judgment dismissing SmithKline's infringement action with prejudice.

38. On February 17, 1998, SmithKline filed suit in the District of Massachusetts against Eon, alleging that Eon's 500 mg and 750 mg generic nabumetone products infringed SmithKline's '639 Patent. SmithKline's suit against Eon was consolidated with, and became a part of, the Copley and Teva Infringement Actions on September 2, 1999.

39. On March 6, 1998, SmithKline filed a second action against Eon, in the Eastern District of New York, setting forth allegations identical to those in its District of Massachusetts action against Eon. SmithKline's second suit against Eon was transferred to this District and subsequently consolidated with the Infringement Actions for all purposes, including trial.

40. The Infringement Actions were consolidated for all purposes and captioned as *In re '639 Patent Litigation*, Civil Action No.97-12416-RCL (D. Mass.) and were assigned to the Honorable Reginald C. Lindsay.

41. By way of defenses and counterclaims to the Infringement Actions, the Generic Manufacturers claimed that the '639 patent was invalid because nabumetone was anticipated by prior art, namely a 1973 article by scientists J.N. Chatterjea and R. Prasad entitled "Condensation of

Mannich Base Salts with Phenols: Orientation of Adducts," published in the *Indian Journal of Chemistry,* Volume 11 at 214-18 (March 1973) (the "Chatterjea & Prasad publication"). The Generic Manufacturers argued that the Chatterjea & Prasad publication identified and enabled nabumetone and therefore anticipated all claims set forth in the '639 patent, either explicitly or inherently. They also claimed that the '639 patent is unenforceable because SmithKline breached its duty of candor to, and engaged in inequitable conduct before, the PTO.

42. Defendants knew that nabumetone was not their intellectual development and was specifically anticipated by prior art; and that Defendants made intentional material misrepresentations to the PTO in order to obtain the '639 patent.

43. For example, an internal SmithKline memorandum dated January 2, 1975, stated that nabumetone "is not the unique SmithKline compound we thought it was." A report from SmithKline's anti-inflammatory group dated January 20, 1975 directly admitted:

> The original [Chatterjea & Prasad] publication pre-dated our patent application and hence we have a case of prior disclosure.

44. A year later, in February 1976, a SmithKline anti-inflammatory group memorandum reiterated the fact that nabumetone was established by prior art and that obtaining a patent was not possible, stating, "The compound is old, and so no claims to [nabumetone] per se or its preparation can be obtained." Notwithstanding these internal admissions, Defendants continued to prosecute their patent application for nabumetone.

45. On March 4, 1977, SmithKline finally informed the PTO of the Chatterjea & Prasad publication, but stated that this publication did not negate SmithKline's claim as to nabumetone. Specifically, Defendants told the PTO that they did not believe there was "a sufficient enabling

disclosure in that brief description in the reference to enable one of ordinary skill in the art to produce the compound." Thus, Defendants asserted to the PTO that the Chatterjea & Prasad publication did not provide enough information to reproduce.

46. Notwithstanding this direct statement to the PTO, on October 17, 1977, an internal SmithKline letter from a member of the SmithKline patent department, advised SmithKline's Canadian patent agents that "submitting affidavit evidence that the Chatterjea & Prasad paper contains inoperative information does not seem possible."

47. Based on Defendants' intentional misrepresentations, on June 9, 1983, the PTO examiner reversed his original rejection of the Defendants' claims, and on December 13, 1983, the PTO issued the '639 patent.

48. An internal Defendants' memorandum, authored after the '639 patent was granted, stated: "All the claims including the unrestricted compound claim have been allowed. The Examiner's decision is completely unexpected. . . . It would appear that this is the first time a patent has been allowed in the U.S.A. for a compound that is described in the prior art under these circumstances."

49. Both before and after the '639 Patent was issued, Defendants knew that the '639 Patent was anticipated by prior art and that the '639 Patent was not enforceable because Defendants and their representatives had knowingly made material misrepresentations to the PTO in connection with the prosecution of that patent.

50. Despite this knowledge, Defendants commenced, prosecuted, and maintained the sham Infringement Actions against the Generic Manufacturers and defended against their counterclaim suits for the improper purpose of maintaining a monopoly in the Relevant Markets, and to conceal by deceit

that unlawful interference and monopoly maintenance.

51. Defendants continued to maintain the sham *Orange Book* listing, the Infringement Actions, and their sham defenses of the counterclaim suits knowingly, intentionally, affirmatively, with the purpose of unlawfully maintaining their monopoly in the Relevant Markets, and with the effect of affirmatively and continuously foreclosing the Generic Manufacturers and any other competitors from the Relevant Markets.

52. On August 8, 1998, the FDA granted "tentative" approval to Eon's ANDA No. 75-280 for Nabumetone Tablets, 500 mg and 750 mg. By granting "tentative" approval, the FDA determined that all the criteria for ANDA "final" approval had been satisfied except for the resolution of issues relating to patents or the 180-day exclusivity period. The tentative approval letter further stated that final approval could not be granted until the resolution of pending patent infringement litigation or the expiration of the 30-month stay.

53. On December 24, 1998, the FDA issued "tentative" approval to Teva's ANDA No. 75-189 for 500 mg and 750 mg nabumetone tablets. The tentative approval letter further stated that final approval could not be granted until the resolution of pending patent infringement litigation or the expiration of the 30-month stay.

54. The Infringement Actions continued without resolution beyond the 30-month Hatch-Waxman stay period. On May 26, 2000, after the expiration of the automatic stay, the FDA granted final marketing approval to Teva's ANDA No. 75-189 with respect to 500 mg nabumetone tablets.

55. On June 6, 2000, the FDA granted final marketing approval to Copley's ANDA No. 75-179 with respect to 750 mg nabumetone tablets.

F. The Court's Ruling Invalidating The '639 Patent

56. A non-jury trial commenced on January 8, 2001, between Defendants and the Generic Manufacturers, and lasted 16 days. On August 14, 2001, Judge Lindsay held that '639 patent was invalid because the 1973 Chatterjea and Prasad publication described nabumetone to the ordinary chemist in 1973 and anticipated claims 2 and 4 of the patent. *In re '639 Patent Litigation*, 154 F. Supp.2d 157, 186-87 (D. Mass. 2001).

57. In addition, the Court held that the '639 patent was unenforceable because Defendants made material misrepresentations to the PTO. Specifically, the Court stated:

> I accepted the recommendations and conclusions of the special master as to the defendants' summary judgment motion on unenforceability. Thus, I have found two material misrepresentations: Dr. Rose's statement, in the Second Rose Declaration, that "had [he] not been in th[e] unusual position [of having the free acid with which to begin his experiment], [he] would have been obliged to prepare the required ... intermediate ... in accordance with ... [Jones], as indeed any independent expert would be obliged because the free acid was not and still is not generally available;" and Dr. Anderson's statement, in his Affidavit, that the melting point of hydroxy ketone was "oil."

Id. at 187.

58. The Court then found that the material misrepresentations made by Defendants were made with the intent of deceiving the PTO, stating:

> Having heard all the evidence at trial, and having judged the demeanor and credibility of the witnesses presented, I conclude that there is clear and convincing evidence that Beecham's misrepresentations were intentional, and that therefore, the '639 patent is unenforceable on the grounds of inequitable conduct.

Id. at 188.

59. In conclusion, the Court held:

> I find that Beecham engaged in a pattern of misrepresentation in its dealings with the PTO so pervasive as to negate any possibility that Beecham's misrepresentations to the PTO were inadvertent "loose language" or otherwise negligently made. Such a pattern bespeaks only deliberate dissembling by Beecham. Accordingly, I find by clear and convincing evidence that the defendants have established their contention that the '639 patent is unenforceable by reason of Beecham's inequitable conduct during the prosecution of the applications that led to the patent.

Id. at 194. The Court then entered judgment in favor of the Generic Manufacturers and against SmithKline for both patent invalidity and patent unenforceability.

60. Defendants filed a timely appeal to the United States Court of Appeals for the Federal Circuit. In an unpublished decision dated August 15, 2002, the Court of Appeals affirmed the District Court's judgment on the grounds that the patent was invalid because it had been anticipated by prior art. *SmithKline Beecham Corp. v. Copley Pharmaceutical, Inc.*, No. 01-1611, 2002 WL 1890708 (Fed. Cir. Aug. 15, 2002). Having affirmed the trial court on the issue of anticipation, the Court of Appeals did not reach the issue of inequitable conduct. *Id.*

61. Defendants filed a timely petition for rehearing and petition for rehearing *en banc* with the Court of Appeals, which was denied. The Court of Appeals issued its mandate on October 23, 2002.

62. On October 30, 2002, Defendants filed a Motion to Clarify the Disposition of the Appeal and Conform the Judgment. The Court denied the motion on November 27, 2002.

63. Teva commenced sales of a 500 mg generic version of Relafen on or about August 20, 2001. Teva commenced sales of its 750 mg generic on or about September 26, 2001.

64. Throughout the course of the proceedings before the PTO and for much of the litigation

of the infringement action, Defendants knowingly, willfully and fraudulently concealed the true facts about the Chatterjea and Prasad publication, their knowledge of the existence of prior art, and their misrepresentations to the PTO in order to wrongfully obtain the '639 patent and to wrongfully prevent and discourage lawful competition with their brand name product Relafen, in the manner more specifically described herein.

65. This fraudulent concealment as described above prevented Plaintiff from learning the truth about Defendants' illegal conduct which would have allowed earlier actions to be commenced. At all times, Plaintiff was kept in ignorance of the information necessary to know that Defendants had engaged in wrongful conduct or that Plaintiff had been harmed by such conduct.

COUNT I

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

66. Plaintiff repeats and realleges the preceding paragraphs as though set forth herein.

67. As described above, Defendants knowingly and willfully engaged in a course of conduct designated to improperly obtain and extend their monopoly power in the Relevant Markets. This course of conduct included, *inter alia*, the following acts: (i) the intentional submission of false patent information to the FDA; (ii) the intentional submission of fraudulent statements to, and omissions of material facts from, the PTO; (iii) the prosecution of baseless, sham patent litigation against the Generic Manufacturers; and (iv) maintaining sham defenses of the counterclaims by the Generic Manufacturers. The result of Defendants' unlawful conduct has been to obtain and extend their

monopoly.

68. Defendants' Infringement Actions constituted sham litigation, in that the suits were objectively baseless due to, *inter alia*, the presence of the Chatterjea & Prasad publication; and in that Defendants' motivation in bringing the actions was to directly interfere with the ability of the Generic Manufacturers to market less expensive generic versions of Relafen that would compete with the brand-name product.

69. Defendants intentionally and wrongfully created and maintained a monopoly power in the Relevant Markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

70. Plaintiff has been injured in its business or property by reason of Defendants' antitrust violation alleged in this Count. Plaintiff's injury consists of being deprived of the ability to purchase less expensive, generic versions of Relafen, and paying higher prices for nabumetone products than it would have paid in the absence of the antitrust violation. The injury to Plaintiff is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

71. Plaintiff, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seeks a declaratory judgment that Defendants' conduct in seeking to prevent competition through the use of the invalid '639 patent violates Section 2 of the Sherman Act.

72. Plaintiff further seeks equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT II

FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

73. Plaintiff repeats and realleges the preceding paragraphs as though set forth herein.

74. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the following Indirect Purchaser States where Plaintiff operates, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

f. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

g. Kentucky: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;

h. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

i. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

j. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

k. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

l. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;